

Attorney General's Statement on Hemp and CBD Products

Updated: March 10, 2021

Background

The Attorney General's office has received questions about the legality of products containing cannabidiol (CBD). CBD is a specific type of cannabinoid that occurs naturally in cannabis plants. Confusion about the legality of CBD products has increased in light of the federal Agriculture Improvement Act of 2018 (2018 Farm Bill, Section 10113), as well as the passage of state legislation including Senate File 599, known as the Iowa Hemp Act, and House File 2581. This memorandum is meant to clarify the legal status of CBD products under Iowa law, provide pertinent information about the legal status of CBD under federal law, provide information to people who are interested in buying or selling CBD products, and clarify enforcement authority.

Hemp and hemp products are not considered to be marijuana as long as the hemp or hemp product has "a maximum delta-9 tetrahyrocannabinol concentration of not more than three-tenths of one percent on a dry weight basis as calculated pursuant to an official test as provided in section 204.8." Iowa Code § 204.2(9)(a). The Iowa Hemp Act now also includes regulation for consumable hemp products, defined as a "hemp product that includes a substance that is metabolized or is otherwise subject to a biotransformative process when introduced into the human

body." Iowa Code § 204.2(2). Iowa Code Chapter 124E, the Medical Cannabidiol Act, permits the manufacturing and distribution of medical cannabidiol (mCBD), subject to licensing requirements. As defined in Iowa Code Chapter 124E, mCBD is any pharmaceutical grade cannabinoid found in a cannabis plant of any preparation thereof that is delivered "in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule." Iowa Code § 123E.2(10). Under this program, Iowa's licensed manufacturers can manufacture mCBD for distribution to individuals with state-issued mCBD registration cards at Iowa's licensed dispensaries. Iowa Code chapter 124E.

Iowa Hemp Act

On May 13, 2019, Governor Reynolds signed SF599, known as the Iowa Hemp Act, and on April 8, 2020, the U.S. Department of Agriculture's ("USDA") approval of the State's plan was published in the Iowa Administrative Bulletin, fully implementing SF599 and allowing for the production of hemp in Iowa. Applications for a license to grow hemp may now be submitted to the Iowa Department of Agriculture and Land Stewardship. On June 17, 2020, Governor Reynolds signed HF2581, which made amendment to the Iowa Hemp Act and allowed Iowans to produce, manufacture, and distribute consumable hemp.

The U.S. Food and Drug Administration's (FDA) current position is that products marketed with therapeutic benefit claims must be approved by the FDA as drugs prior to introducing them into interstate commerce. The FDA also takes the position that it is illegal to introduce food containing CBD or THC into interstate commerce or to market products containing CBD or THC as dietary supplements. The FDA has published guidance detailing its approach to regulating

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¹ https://www.legis.iowa.gov/docs/aco/bulletincontent/04-08-2020.Bulletin_Component_1183589028181970.pdf

² https://iowaagriculture.gov/hemp

cannabis and cannabis-derived products such as CBD including a list of FDA-approved drugs.³ HF2581 permits the intrastate marketing and sale of consumable products containing CBD or THC. Businesses interested in either manufacturing or selling consumable hemp products in Iowa must first register with the Department of Inspections and Appeals and comply with state requirements for testing, documentation, and labeling.⁴ The possession, use, manufacturing, marketing, transporting, delivering, or distributing of a product containing hemp intended for consumption through inhalation is still prohibited and considered a serious misdemeanor. Iowa Code § 204.14A.

Consumer Advisory

Consumers should be aware that CBD products advertised for human consumption are not regulated for quality by the FDA. Consumers should take care when purchasing items either in person or online as only consumable hemp products produced and manufactured in Iowa will be subject to the state's regulation and inspection. Products not strictly regulated and regularly inspected carry the risk of containing contaminants, such as heavy metals or pesticides. The quantity of CBD or THC advertised on a product produced by an unregistered or out-of-state producer may not accurately reflect the true composition of the product. In 2017, a study published in JAMA found that out of 84 products sold online, 43% had more CBD than advertised and 26% had less CBD. Products on the market, especially those sold online, as containing CBD may not contain any CBD at all. Some of these products may contain more than 0.3% THC, even when

³ https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

⁴ <u>Registration opens for consumable hemp manufacturers and retailers | Iowa Department of Inspections & Appeals</u>

⁵ Marcel O. Bonn-Miller et al., *Labeling Accuracy of Cannabidiol Extracts Sold Online*, Journal of the American Medical Association, Nov. 7, 2017, at 1708.

advertised as being derived from hemp. Consumers should strive to ensure that any consumable hemp product purchased in the State of Iowa is in compliance with the production, manufacturing, and labeling requirements under Iowa's Hemp Law and appropriately registered with the Iowa Department of Inspections and Appeals. Consumers are encouraged to report to DIA businesses known to be in violation of these requirements. In addition, consumers should be cautious about any CBD product claiming to treat or cure serious diseases or ailments. Iowa Code chapter 124E governs mCBD, including a list of conditions approved to be treated by mCBD, and a consumer should never cease taking prescribed medications in favor of taking CBD products without consulting a licensed health care provider.

The FDA has used, and intends to continue using, its authority to take action against companies that sell CBD products that put consumers at risk. In particular, the FDA is concerned about products with unproven claims to treat serious or life-threating diseases, which can lead patients to opt to forgo available treatments in favor of an unproven product. The FDA has issued several warning letters to distributors of CBD products, which are posted for public viewing on its website. Distributors of CBD products should also be aware that strict product liability laws may make the seller of a dangerous product liable to a person injured by that product, even if the product was manufactured by another entity. Finally, farmers who are considering growing hemp in Iowa under the IDALS program should familiarize themselves fully with the legal requirements and market conditions for hemp products before making investments. HF2581 provides guidance on the production, manufacturing, packaging, and labeling on such products.

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⁶ FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity | FDA

⁷ https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results- cannabidiol-related-products

Enforcement

Although consumable hemp, as regulated by states, is not FDA approved or otherwise federally regulated, the FDA has not taken affirmative enforcement action against states that have legalized consumable hemp. The FDA's lack of action to date should not be taken as a tacit permission or approval by the federal government. Businesses engaged in the production, manufacturing, delivering, or distributing of hemp, hemp products, or consumable hemp should be aware of all federal regulations governing hemp in interstate commerce. Consumers and sellers of CBD products should understand that, because not all products are legal under Iowa or federal law, local and federal law enforcement agencies retain the authority and discretion to take criminal enforcement action against people who sell or possess over-the-counter CBD products that are not compliant with the law. In addition, the Office of the Attorney General has the authority to take enforcement action against any person for false or misleading advertisements or deceptive sales practices related to CBD products.

The Iowa Department of Inspections and Appeals (DIA) has jurisdiction over an entity that sells CBD products, as it licenses and regulates entities that sell or serve food, unless an entity sells only pre-packaged and non-temperature controlled foods. DIA also administers the Consumable Hemp Regulatory Program, responsible for the regulation or consumable hemp products. Registration and sales of such products began on March 3, 2021. No sales may commence until a manufacturer or retailer has an approved registration through DIA. The Iowa Alcoholic Beverages Division (ABD) licenses and regulates those who sell and serve alcoholic beverages. The ABD issued a regulatory bulletin on June 14, 2019, to license and permit holders indicating that both

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⁸ https://dia.iowa.gov/consumable-hemp

CBD and THC are prohibited in alcoholic beverages sold in Iowa.⁹ This bulletin has yet to be changed, updated, or replaced in light of HF2581.

The Iowa Department of Agriculture and Land Stewardship ("IDALS") maintains that CBD/hemp is not allowed to be added to meat/poultry products or dairy products over which IDALS has regulatory authority, notwithstanding the provisions in HF 2581. The sale of meat/poultry products that are considered adulterated is prohibited, ¹⁰ and "adulterated" includes a product containing CBD/hemp. ¹¹ The United States Department of Agriculture ("USDA") has also notified IDALS that CBD has not been generally recognized as safe ("GRAS") as a food ingredient or additive and is not allowed in USDA-inspected products. ¹² For dairy products, Iowa law allows only "grade 'A' pasteurized milk and milk products shall be sold" within the State, and the sale of adulterated dairy products is prohibited. ¹³ In addition, Iowa is required to adopt the Grade A Pasteurized Milk Ordinance ("PMO"), which the agency has done. ¹⁴ The 2019 PMO prohibits the sale of any adulterated dairy products, ¹⁵ and dairy products containing CBD/hemp have not been recognized as GRAS by FDA or USDA.

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⁹ https://abd.iowa.gov/sites/default/files/regulatory_bulletin_-

thc and cbd in alcoholic beverages 0.pdf

¹⁰ See Iowa Code section 189A.10(1)(b)(1) and (2) (defining a fraudulent practice as selling an adulterated meat/poultry product).

¹¹ Iowa Code section 189A.2(1)(b)(3) defines "adulterated" as "[i]f it bears or contains any food additive which is unsafe within the meaning of section 409 of the federal Food, Drug, and Cosmetic Act;" *see supra* note 3.

¹² IDALS has adopted portions of the regulations issued by the USDA under the Federal Wholesome Meat Act, including, but not limited to, the federal regulation that prohibits a meat or poultry product from containing any food ingredient that would render it adulterated. See 21 Iowa Admin. 76.2 (adopting 9 C.F.R. § 424.21(a)(1) by reference).

¹³ Iowa Code § 192.103(1)-(2); *see* Iowa Code § 190.5(3)(A dairy product is considered adulterated if "it consists, in whole or in part, of any substance unfit for human consumption."). ¹⁴ *See* Iowa Code §§ 190.2(1)-(2) and 192.102.

¹⁵ See 2019 PMO, Section 2, p. 15 (available at https://www.fda.gov/media/140394/download).

Stores that are not licensed and regulated by a state agency remain subject to enforcement at the discretion of local law enforcement. Businesses and consumers that have further questions, including questions about the legality of a specific product, should contact a private attorney.

Warning for Farmers

Claims are abundant that farmers can "make a killing" growing hemp. But regulators have seen irrational exuberance over alternative crops before, and the potential for fraud and overstated returns is high. The Iowa Department of Agriculture and Land Stewardship advises growers to do their research and confirm there is a viable, profitable market for commercial hemp production before they make an investment in seed and equipment. Growers and landowners should ask for documented returns and seek contracts that spell out payment details.